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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/459,522 12/13/99 CRUMP

C 041861-01500

EXAMINER

QM12/0606

LOCKE LIDDELL & SAPP LLP
ATTN: IP DOCKET CLERK
600 TRAVIS
SUITE 3400
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EREZO, D
ART UNIT

PAPER NUMBER

3761
DATE MAILED:

06/06/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/459,522

Applicant(s)

CRUMP ET AL.

Examiner

Darwin P. Erez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 2-4, 9 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. In Claim 2, line 2, "distal position" is indefinite, it is unclear as to what area is distal in regards to the flap movement.
4. In Claim 2, line 2, "proximal position" is indefinite, it is unclear as to what area is proximal in regards to the flap movement.
5. Claim 3 recites the limitation "the distal end of the catheter" in line 2. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 6 recites the limitation "the diameter of the disk" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.
7. Claim 9 recites the limitation "the orifice" in line 2. There is insufficient antecedent basis for this limitation in the claim.
8. Claim 15 recites the limitation "the patient" in line 5. There is insufficient antecedent basis for this limitation in the claim.
9. Claim 18 recites the limitation "the airflow" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **Claims 1; 2; 3; 4; 5; 6; 7; 8; 9; 10; 11; 12; 13; 22; 23; 24; 25 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 22; 2, 19; 11; 19, 20; 1, 4; 5, 6; 2, 7; 12; 12; 15, 32; 1, 5, 22; 22; 28; 35; 36; 37; 38 of copending Application No. 09/460,257, respectively.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations claimed in the instant application are also claimed in the copending application, e.g., an apparatus comprising a catheter, a manifold, a valve having a flap, a catch, a flap pivotally connected to the manifold, an aperture, a collar, a port for injecting liquid into the collar, protrusion formed on the flap, a first and second seal, a valve comprising at least one injection molded medical grade synthetic resin, and a valve composed of a material from the same group of polymers, and including similar functional limitations set forth by the Applicant in both applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. **Claims 1, 4-7; 2; 3; 8; 9; 11, 12; 13; 14; 15, 16; 17; 20; 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1; 19; 16; 21; 6; 16; 16, 17; 16, 17, 18; 29, 30; 21, 29, 30; 29, 30, 32; 27 of U.S. Patent No. 6, 227,200, respectively, and in view of U.S. Patent No. 6,168,758 to Forsberg et al.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the structural limitations claimed in the instant application are also claimed in the patent, e.g., an apparatus comprising a catheter, a manifold, a valve disposed in the manifold, a catch disposed in the manifold, a valve comprising a flap, a flap with at least one protrusion, a valve with an open and closed position, a valve with an aperture, a collar in the manifold, a flap configured to frictionally engage the distal end of the catheter, a first and second wiper seal, a valve with a pivotable flap, and including similar functional limitations set forth by the Applicant in the instant application and the patent.

The difference between Crump et al. and Claim 22 is the valve comprising at least one injection molded medical grade synthetic resin.

Forsberg et al. discloses a liquid assay device comprising a valve composed of polyether block amides (col. 6, lines 38-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any well known material, including the polyether block amides of Forsberg et al, because it is a mere substitution of one valve material

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for another. Also, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice. *Sinclair & Carroll Co. V. Interchemical Corp.*, 327, 65 USPQ 297 (1945) also note *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Claims 23-25 are equivalent in scope to Claim 22 discussed above and are included in *Crump et al.* modified by *Forsberg et al.*

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claim 1, 11, and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,490,503 to Hollister.

Hollister discloses an apparatus comprising a suction catheter **1** configured for removing fluids from a respiratory tract of a patient and having a distal end configured for suctioning secretions from the respiratory system of a patient; a protective sleeve **2** surrounding a proximal longitudinal portion of the catheter; a manifold **4** defining a ventilation circuit disposed in communication with the catheter to be advanced through the ventilation circuit of the manifold and into the respiratory tract of the patient; and a valve **70** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit and for at least partially occluding the distal

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end of the catheter, the valve being capable to frictionally engage the distal end (col. 2, lines 1-45), wherein the valve comprises at least one protrusion **82, 84** on at least one surface of the valve.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 2, 5, 7-10^{12, 16, 17} are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollister in view of U.S. Patent No. 5,582,161 to Kee.

Hollister discloses all the limitations of the above mentioned claims but fails to teach a valve comprising a flap movable between a first, distal position, and a second, proximal position.

Kee discloses a valve comprising a flap **20** movable between a first, distal position, and a second, proximal position (col. 4, lines 49-61).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to employ the valve of Kee to that of Hollister because the valve of Kee is capable of closing off the distal end of the adapter to increase sanitary protection (col. 2, lines 6-10; col. 3, lines 54-60).

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17. As to Claim 5 and 16, the combination of Hollister and Kee discloses a flap pivotally connected to the manifold and disposed to selectively separate the distal end of the catheter.

18. As to Claim 7, the above combination discloses a valve with an open and closed positions and wherein friction maintains the valve in a nearly closed position (the flaps **20** are pushed against each other).

19. As to Claim 8 and 17, Kee teaches a valve with an aperture and the flaps **20** covering the aperture (col. 4, lines 50-53).

20. As to Claim 9, Hollister teaches an apparatus comprising a collar **50** disposed in the manifold and wherein an orifice is formed in the collar.

21. As to Claim 10, Hollister teaches a collar **50** including a port **62** for injecting liquid into the collar.

22. As to Claim 12, Hollister teaches a first and second wiper seal disposed about the catheter when the catheter is advanced in the manifold (Fig. 4, **80**).

Conclusion

23. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 6,070,582 to Kee.

U.S. Patent No. 5,513,628 to Coles et al.

U.S. Patent No. 5,598,840 to lund et al.

U.S. Patent No. 5,642,726 to Owens et al.


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24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss can be reached on (703) 308-2702. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe
June 3, 2001


GLENN K. DAWSON
PRIMARY EXAMINER